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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,763	09/17/2001	Paul J. Thompson	11576.51USI1	8878

23552 7590 01/30/2004

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EXAMINER	
ROBERTS, PAUL A	
ART UNIT	**PAPER NUMBER**
3731	8

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,763	THOMPSON ET AL.	
	Examiner	Art Unit	
	Paul A Roberts	3731	

-- The MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *12,15,16,22 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-14, 17-21, 23, 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 7*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 23 recites the limitation "said stent" in line 2. There is insufficient antecedent basis for this limitation in the claim. Note claim 23 provides antecedent basis for a stent mounting location and a stent arrangement, but not a stent itself.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 4, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Dusbabek et al. (Dusbabek) 6,203,558. The elements of claim 1 are shown in the attached figure. The admission port is element 15 in figure 1. Element 28 is disclosed by Dusbabek to be a fluid lumen. It acts to deploy fluid from the admission port into the fluid channel. Element 28 is considered to fall within the scope of a spacer because its presence inherently helps prevent the fluid channel from being compressed. Element 28 is roughly 25% of the size of the fluid channel. Regarding claim 20, the discharge opening is the location where element 28 is pointing.

3. Claims 25, 28, 29, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Fiedler '109. Fiedler discloses the elements of claim 25. Said elements have been labeled on an attached figure. Element 34 is the admission port. The fluid exchange aperature is the gap that exists when the outer member is retracted. This is the pathway where the fluid can flow out of the device. The stent is self-expanding. The stent is deployed by sliding the outer member relative to the inner member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-9, 17, 18, 19, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler US 6605109 in view of Ponzi US 5964757. Regarding claim 1, the elements of claim 1 have been labeled on an attached figure. Element 38 is the spacer. Element 34 is the admission port. The spacer of Fiedler is clearly not 10% of the fluid channel length. The fluid channel length is indicated by the dotted lines. There are improved ways one could build the Fiedler device to ensure that the inner and outer tubes remain separated. Ponzi teaches using a spacer shown as element 20, which runs the length of the analogous outer tube 22. "The spacer 52 provides a transition in flexibility at the junction of the catheter body 12 and catheter tip 14, which allows the junction of the catheter body 12 and tip section 14 to bend smoothly without folding or kinking." This advantage is important because if there are kinks in the tubes, the tubes

will not be able to slide within each other. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the spacer of Fiedler with the spacer of Ponzi because Ponzi discloses that his spacer is designed to prevent the kinking or folding of the inner and outer members. Regarding claims 2-8, the combined device has a spacer running the entire length of the section. Regarding claim 9, the spacer does offset the inner member from the outer member. Regarding claims 17 and 18, a surface capable of being thermally bonded is considered to be within the scope of a thermal bonding surface. Ponzi discloses said surface in figure 3. Regarding claim 19, the inner tubular member is hollow. Regarding claim 23, the stent mounting location comprises a self-expanding stent arrangement; the stent is exposed by retracting the outer tubular member.

5. Claims 1, 10-11, 13 and 14, 17, 18, 19, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler US 6605109 in view of Divino Jr et al. (Divino) US 66767900. Regarding claim 1, the elements of claim 1 have been labeled on an attached figure. Element 38 is the spacer. Element 34 is the admission port. The spacer of Fiedler is not a spline. The fluid channel length is indicated by the dotted lines. There are improved ways one could build the Fiedler device to ensure that the inner and outer tubes remain separated. Divino teaches using a spacer shown as element 72. Divino describes them as fins. Fins are considered to be within the scope of splines. Divino discloses using a plurality of fins. The advantage of using fins as opposed to the single spacer element in Fiedler is that the fins will provide kinking protection along the length of the fluid channel length. At the time of the invention it would have been obvious to one having ordinary skill in the art to substitute the Fiedler spacer with the spacer as taught by Divino, because a fin type spacer provides support against kinking and bending of the

inner and outer tubular members. The fins are radial, spaced –apart members. Regarding claims 17 and 18, a surface capable of being thermally bonded is considered to be within the scope of a thermal bonding surface. Divino discloses said surface in figure 4a. Regarding claim 19, the inner tubular member is hollow. Regarding claim 23, the stent mounting location comprises a self-expanding stent arrangement; the stent is exposed by retracting the outer tubular member.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dusbabek '558 in view of Matsuda et al. 5,840,066. Dusbabek discloses all of claim 1 as disclosed supra. The Dusbabek fluid port is intend to be used as a means to inflate the balloon. This does not provide anticipation of an opening designed to permit fluid flow from said channel to a patient's lumen. However, it is well known in the art to add an additional fluid port to a catheter system to squirt various types medicine into the region where the operation is taking place. This is preferable because it allows the medicine to administered locally to the region requiring it. Adding such a port to the Dusbabek device would increase the functionality of the device (combination stent/medicine deployer). Often deploying stents can irritate the vessel and various anesthetics, antibiotics, etc. can be deployed using a medicine port. Matsuda et al. discloses the use of a medicine port on the distal end of a balloon catheter to deliver medicine to a specific region. At the time of the invention it would have been obvious to one having ordinary skill in the art to add the medical discharge apparatus of the Matsuda device to enable the Dusbabek device to deploy medicine.

7. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler '109 in view of Matsuda et al. 5,840,066. The Fiedler fluid port is intended to be used as a means to deploy the stent. This does not provide anticipation of an opening that extends radially

through the outer tubular member. However, it is well known in the art to add an additional fluid port to a catheter system to squirt various types medicine into the region where the operation is taking place. This is preferable because it allows the medicine to administered locally to the region requiring it. Adding such a port to the Fiedler device would increase the functionality of the device (combination stent/medicine deployer). Often deploying stents can irritate the vessel and various anesthetics, antibiotics, etc. can be deployed using a medicine port. Matsuda et al. discloses the use of a medicine port on the distal end of a balloon catheter to deliver medicine to a specific region. At the time of the invention it would have been obvious to one having ordinary skill in the art to add the medical discharge apparatus of the Matsuda device to enable the Fiedler device to deploy medicine.

8. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler '109 in view of Little US 5005584. The Fiedler reference anticipates all the limitations of claim 25, but does not disclose a means to measure fluid pressure within the passageway. Little discloses a guidewire insertable through the Fiedler device that is capable of measuring fluid pressure. The combined system is capable of measuring fluid pressure within the passageway. At the time of the invention it would have been obvious to one having ordinary skill in the art to add the Little pressure measurer to the Fiedler system to enable a surgeon using the Fiedler system to determine the pressure of the blood in the lumen where the operation is being performed.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler '109 in view of Bigus et al. (Bigus) 6629992. Fiedler discloses the device of claim 25, but doesn't disclose a sheath. The Bigus device discloses a sheath comprising apertures. The sheath can be used to delivery therapeutic agents to vessel wall to improve healing. At the time of the

invention it would have been obvious to one having ordinary skill in the art to add the Bigus sheath to the Fiedler device to allow the Fiedler device to deliver therapeutic agents via the sheath.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following are guidewire systems using stent delivery methods: Healy et al. 6613075; Buelna et al. 5653689; Barry 2002/0077592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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01/23/04

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

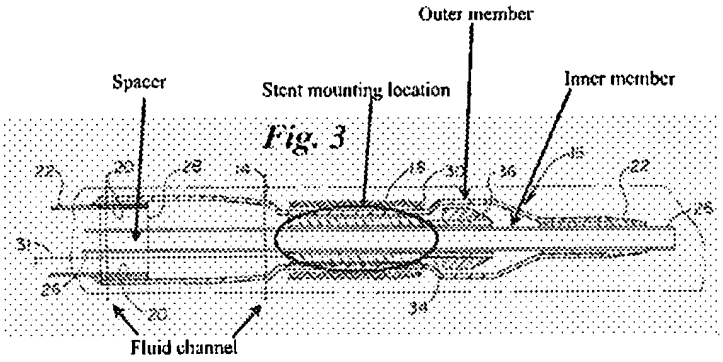
Outer member
Spacer
Stent mounting location
Inner member
Fluid channel

Fig. 3

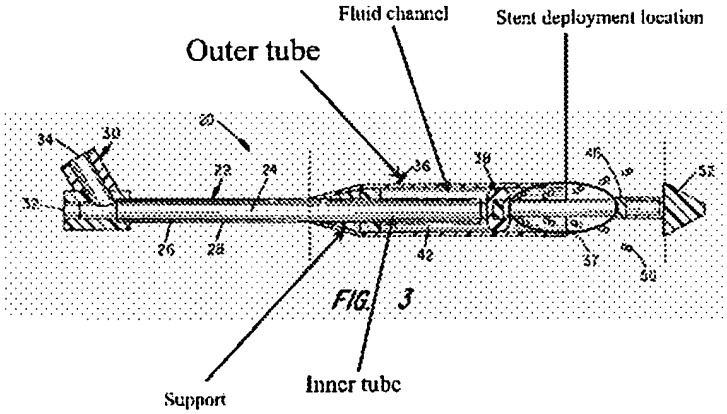
Fluid channel
Stent deployment location
Outer tube
Support
Inner tube

FIG. 3